

**REMARKS**

Reconsideration and withdrawal of the rejections of this application, and, if necessary, an early interview with the Examiner and SPE Deborah Reynolds, are respectfully requested in view of the amendments and remarks.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-18 are pending. Claims 1-11 and 14 are amended and new claims 15-18 are added. No new matter has been added.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. § 112. The amendments and remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the remarks made herein are made simply for clarification.

Further, as noted in Applicants' October 28, 2002 Response to Restriction and Election of Species Requirements, the species listed in claim 9 are not too great in number and can be searched without serious burden. The present invention relates to a DNA vaccine comprising (i) a naked DNA containing and expressing *in vivo* a polynucleotide encoding an antigenic polypeptide; and (ii) at least one adjuvant which is a polymer of acrylic or methacrylic acid or a copolymer of maleic anhydride and alkenyl. The antigenic polypeptide can be an antigen of a pig, horse, dog, bovine, cat or avian pathogen. The present claims, therefore, represent a web of knowledge and continuity of effort that merits examination in a single application. All the pathogens listed in claim 9 relate to a pig, a horse, a dog, a bovine, a cat or an avian. It is respectfully submitted that the species are each related to one another and directed to the same inventive concept.

Moreover, the group of equine pathogens: equine rhinopneumonia virus, equine influenza virus, Cl. Tetani, Eastern encephalitis virus, Western encephalitis virus, Venezuelan encephalitis virus, B. burgdoferi, and rabies virus could be searched and examined together without undue burden because these pathogens all relate to a horse. A search of the elected species—equine influenza virus, an equine pathogen—will touch upon other equine pathogens mentioned above. Simply, a search of any one of these major equine pathogens will uncover art relating to the remainder of these equine pathogens, such that there is no undue or serious burden in examining

all of these equine pathogens in this application. And, new claims 15-18 reflect these aspects of the invention.

Moreover, an inventive concept is the use of the adjuvant with the DNA of the DNA vaccine, such that the species of claim 9 are not too great in number in view of this inventive concept.

Therefore, the request for species election should be reconsidered and withdrawn, or regrouped, e.g., so that at least all equine pathogens are searched and examined together in this application.

## II. THE ART REJECTIONS ARE OVERCOME

Claims 1, 2, 4, 10, 11, and 12 were rejected in the Office Action under Section 103 based on Ross, U.S. Patent No. 6,444,799. The Section 103 rejections must fail on the simple fact that Ross is not prior art.

The Examiner helpfully noted that the claims were rejected “[t]o the extent that applicant has not acknowledges on record that the priority French application is present in any of the parent case or that the French priority document is not present or accessible for the examiner’s consideration . . .” (*Office Action* at 2). The present application claims priority to French Patent Application No. 98/04409, filed on April 3, 1998. A verified English translation of this French priority application is enclosed or will follow shortly. French patent application 98/04409 substantially conforms to PCT/FR99/00666, filed on March 22, 1999. By the verified English translation and remarks herewith, it is clear that the present application is entitled to its priority filing date April 3, 1998; and, it is respectfully requested that the present application be fully accorded its priority filing date of April 3, 1998.

Ross issued from USSN 09/221,017, filed December 23, 1998. Ross is not available against the present application. The present application has an effective filing date of April 3, 1998; an effective filing date prior to the US filing date of Ross. Ergo, Ross is not prior art as to the present application.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103 as to Ross are respectfully requested.

Claims 1-13 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over WO 98/03198 (“WO ‘98”) taken with Miles, Inc. (EP 0 532 833 A1), Lowell (WO 95/11700), and

Lund (U.S. Patent No. 3,920,811). In addition, claims 1 and 14 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over WO 98/03198 taken with Miles, Inc. (EP 0 532 833 A1), Lowell (WO 95/11700), and Lund (U.S. Patent No. 3,920,811).

The Office Action cited WO'198 under 35 U.S.C § 102(e). WO'198 IS NOT available under Section 102(e) as it was published in English from a PCT application filed on or after November 29, 2000.

Moreover, the Office Action admits that WO'198 “does not teach an incorporation of an adjuvant in the DNA vaccine.”

Miles related to an inactivated EHV vaccine.

Lowell related to antigen (protein) vaccines.

And Lund involves an adjuvant for antigens, (see '811 patent claim 1), e.g., killed influenza, clostridium (see 811 patent examples).

All of the secondary documents cited (Miles, Lowell, Lund) relate to classical vaccines—vaccines that upon administration present an epitope or antigen to the immune system—in contrast to a DNA vaccine as in the instant application which expresses an epitope or antigen *in vivo*. That the adjuvants of the instant claims so function to enhance immunogenicity of that which is expressed by the DNA vaccine is surprising and unexpected; and, there is no motivation from the cited documents to employ the adjuvants of the instant claims to DNA plasmid vaccines.

Accordingly, the Section 103 rejections cannot stand.

Reconsideration and withdrawal of the Section 103 rejections are respectfully requested.

### **III THE SECTION 112 REJECTION IS OVERCOME**

Claims 1 and 14 were rejected under Section 112, second paragraph, for containing a trademark. Claim 14 has been amended to recite the generic description of the product, which is found on page 3 of the specification. Claim 1 does not contain a recitation of a trademark product. Therefore, reconsideration and withdrawal of the rejections under Section 112, second paragraph, are requested.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview is respectfully requested, with the Examiner and his SPE, Deborah Reynolds; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**


In view of the amendments, remarks and documents herewith, Applicants have addressed and overcome all rejections of the application set forth in the Office Action, and the present application is in condition for allowance.

Thus, early and favorable reconsideration and withdrawal of the rejections of the application as set forth in the Office Action, and, prompt issuance of a Notice of Allowance of claims 1-18, or an interview with supervisory review, i.e., an interview including Deborah Reynolds, at an early date, with a view towards reaching agreement on allowable subject matter, are earnestly solicited.

Respectfully submitted,

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